

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)	
)	
<i>Plaintiff / Counterclaim-Defendant,</i>)	Case No. 20-125 (LPS)
)	CONSOLIDATED
v.)	
)	JURY TRIAL DEMANDED
ARCHERDX, INC., ARCHERDX, LLC and)	
INVITAE CORP.)	HIGHLY CONFIDENTIAL -
)	ATTORNEYS' EYES ONLY
<i>Defendants / Counterclaimants.</i>)	
)	

**DEFENDANTS' OPPOSITION TO NATERA, INC.'S MOTIONS FOR PARTIAL
SUMMARY JUDGMENT AND TO PRECLUDE CERTAIN EXPERT TESTIMONY**

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I. INTRODUCTION

Natera requests summary judgment on seven different issues and seeks to exclude expert testimony on two additional topics. For each of Natera's nine issues, however, Natera presents only superficial arguments that both ignore underlying factual disputes and misapply the law. Natera's arguments are cursory not because the issues are clear and simple, but because Natera disregards evidence that undermines its positions, including its own admissions to the public and Patent Office, the testimony of its employees and experts, and its own internal documents. Willful blindness to important evidence is a hallmark of Natera's motion—a tactic that makes plain Natera's inability to establish that there are no genuine issues of material fact or grounds for exclusion of testimony. Natera's motion should be denied in its entirety.

II. RESPONSE TO NATERA'S REQUESTS FOR SUMMARY JUDGMENT

A. Summary Judgment Of No Indefiniteness Is Unwarranted

1. The “Melting Temperature” Term In The ’708 Patent Is Indefinite

Natera posits that the claim term “a melting temperature of the at least 2 primers” is not indefinite because it is “undisputed” that “as of 2014...two methods disclosed in the patent – the empirical ultraviolet method and the Primer3/Santa Lucia software method – would result in melting temperature values within only 1°C of difference.” D.I. 432 at 30-31. As documented herein, however, to make this argument Natera actually relies on methods by Owczarzy that the patent does *not* mention in the slightest. *See id.* at 32-33.

Natera’s assertion that to determine primer melting temperatures one should use sundry undisclosed methods is not new. As Defendants explained in their opening brief in support of their motion for summary judgment, Natera previously informed the public and Patent Office that one could use the undisclosed Bolton and McCarthy technique to determine melting temperatures.

D.I. 430 at 18-19. This admission, Defendants explained, showed perhaps more than anything that Natera's claims are indefinite. *Id.* at 19.

The arguments Natera presents in its summary judgment brief have now replaced Natera's prior assertions to the Patent Office as the most compelling evidence of indefiniteness. The techniques Natera now relies upon are not just unmentioned in the patent but are also expressly disfavored by the software that Natera says the skilled artisan should use (which is also unmentioned in the patent). Although Natera leans heavily on the Court's earlier claim construction ruling, the Court did not foreclose development of the record on the indefiniteness issue. *See* D.I. 243 at 12. Natera's most recent arguments prove definitively that, rather than teaching consistent methods that yield equal melting temperatures, the patent teaches two different techniques that give divergent results, such that the skilled artisan following the patent would be unable to assess infringement reliably.

a. Background Of The "Melting Temperature" Indefiniteness Dispute

The claim limitation at issue is "the annealing temperature for the reaction conditions is greater than a melting temperature of the at least 2 primers." Natera argues that the '708 patent discloses two methods, "the empirical ultraviolet method and the Primer3/Santa Lucia software method," for computing these melting temperatures. D.I. 432 at 30-31. This limitation is at the claimed point of novelty.

In the context of the claims, a melting temperature difference of just one degree or more between methods is sufficient to result in indefiniteness due to a minimum one-degree relationship between "annealing temperature" and "melting temperature." *See* D.I. 433-2 at 3:42-49, 6:45-51, 79:62-80:30. Natera admits that the threshold for materiality is one degree. *See* D.I. 432 at 32 n.8. It is undisputed, however, that the UV and Primer3/SantaLucia methods give results that

are *greater* than one degree apart. *See* D.I. 430 at 21-22. Natera’s expert even admitted that the overall average difference between the two methods is greater than one degree. *See* D.I. 434, Ex. A ¶ 311. In fact, as Defendants explained in their opening brief in support of summary judgment, the difference is actually far greater than one degree. *See* D.I. 430 at 21. The significantly different primer melting temperatures resulting from the UV and Primer3/SantaLucia methods render the ’708 patent claims indefinite.

Attempting to remedy this, Natera now contends that “improvements made by Owczarzy and colleagues to the Primer3/Santa Lucia software—published in the publication Owczarzy 2008 (Ex. 33) —allowed the difference between software calculated melting temperatures and those measured by the empirical method to be within less than 1°C.” D.I. 432 at 32. The ’708 patent, however, never once refers to the Owczarzy “improvements.” Notably, Natera’s arguments regarding Owczarzy are absent from its expert’s report. Natera raises this argument for the first time on summary judgment.¹

b. Natera’s Attempted Owczarzy Remedy Confirms Indefiniteness

Even if it is true that the Owczarzy “improvements” bring the Primer3/SantaLucia and UV methods into some sort of alignment, Natera’s reliance on Owczarzy is without merit and further confirms that the patent is indefinite.

¹ Natera argues that Owczarzy was considered during claim construction. *See* D.I. 432 at 32. This is inaccurate. There, Natera cited Owczarzy only once for the proposition that the Primer3 software was a “less costly surrogate” of the UV method. D.I. 177 at 73-74. Natera never argued that the patent discloses a version of Primer3 that includes Owczarzy or that a skilled artisan would even use the Owczarzy option given such a Primer3 version.

First, and most important, the patent never once mentions the Owczarzy techniques, a point Natera does not deny.² Given that the patent never mentions Owczarzy, and given that Natera argues Owczarzy is needed to bring the two techniques that *are* actually mentioned in the patent into alignment, Natera admits that the patent at the very most teaches two different techniques that give different results. Far from establishing that Natera is entitled to a summary judgment of definiteness, this proves *indefiniteness*.

Natera nonetheless notes that the patent refers to Primer3 software, and argues that some undisclosed version of this software that existed “as of 2014,” which is the priority date of the patent, implements Owczarzy. D.I. 432 at 31. By its use of the phrase “as of 2014,” however, Natera is at best intentionally vague and at worst misleading. In fact, all examples and disclosures regarding Primer3 in the ’708 patent are directed to the pre-2014 version 2.2.3 of Primer3. *See, e.g.*, D.I. 433-2 at 47:49-53, 61:38-41, 218:25-29, 231:3-7. The ’708 patent even copies parts of the version 2.2.3 manual. *Compare* D.I. 433-2 at 235:48-236:43 with D.I. 434, Ex. R at 25-26. It is undisputed that version 2.2.3 of Primer3 does *not* include Owczarzy.

There were indeed versions of Primer3 prior to the 2014 priority date of the patent that included Owczarzy and other variants. But none of them are referenced in the patent. Natera could have mentioned such software versions, but it did not. Natera cannot now incorporate these unspecified Primer3 versions into the ’708 patent by using the phrase “as of 2014” in its summary judgment brief.

Second, even if one assumed the skilled artisan would understand from the patent that one should use a version of Primer3 that the patent does not mention, but that includes Owczarzy, this

² Natera’s argument that Defendants’ expert did not evaluate Owczarzy is without merit since neither the patent nor Natera’s experts, as explained in Part II.A.1.c, mention Owczarzy.

would not cure the indefiniteness problem. This is because all versions of Primer3 that include Owczarzy “as of 2014” explicitly tell the user **not** to use the Owczarzy technique. The manuals for all seven Primer3 version specifically point out that the option to use Owczarzy is part of a set of options that is “not the default” and not “recommended:”

The handling of divalent cations when PRIMER_SALT_CORRECTIONS=2 (**not the default and not the recommended value**) has been updated. The rationale is that, when divalent cations are present, the formula by Owczarzy et al., 2004 (used previously by Primer3) can be improved upon as described in (Ahsen et al., 2010; Owczarzy et al., 2008). Therefore we have updated the melting temperature calculation to follow the scheme in Figure 9 of (Owczarzy et al., 2008). Please find references to these papers below in the manual.

Ex. H at 4,³ Ex. I at 4; Ex. J at 4; Ex. K at 4; Ex. L at 4; Ex. M at 4; Ex. N at 4.

Natera, which relies upon the Primer3 2.2.3 manual’s “recommended” setting to argue for the disclosure of the SantaLucia parameters, cannot now suggest that the Primer3/SantaLucia method should actually be augmented with an undisclosed variant that is “not the recommended value.” Natera submits no expert witness testimony to justify why a skilled artisan following the patent would ever think to use such undisclosed and disfavored techniques, as compared to the many other variants and settings that are available.

c. Natera Has No Admissible Evidence To Support Owczarzy

Even if Natera’s reliance on Owczarzy to remedy the significant difference between the UV and Primer3/SantaLucia methods was not so fundamentally flawed, it cannot prevail at summary judgment, or defeat Defendants’ summary judgment motion, for the simple reason that Natera has no admissible evidence it can present on Owczarzy.

³ Emphasis supplied unless otherwise noted. Exhibit cites are to exhibits attached to the accompanying declaration of Edward Reines.

Natera repeatedly describes the Primer3 software “as of 2014” to reference Primer3 versions not disclosed in the ’708 patent. Neither of Natera’s technical experts, however, provided any opinions on any of these Primer3 versions to show the implementation of Owczarzy, nor did they provide opinions on Owczarzy itself. *See generally* Ex. A; D.I. 353 at Ex. 14. Other than these two technical experts, Natera has not provided any disclosure of expert testimony from the inventors or other Natera scientists pursuant to Rule 26(a)(2)(C). Thus, Natera has no expert testimony on its flawed Owczarzy theory.

Furthermore, none of the ’708 patent inventors have any foundation to provide fact testimony on Owczarzy, even as non-experts. Dr. Zimmermann, one of the inventors, stated during deposition that [REDACTED]

[REDACTED]. *See* Ex. B at 127:8-9, 128:5-6, 253:14-20. Dr. Rabinowitz, another inventor, admitted during deposition that [REDACTED]

[REDACTED]. *See* Ex. C at 152:24-153:13. Mr. Dodd, another inventor, was unable to recall during deposition [REDACTED]

[REDACTED] *See* Ex. D at 78:5-16, 109:1-13. Dr. Hill, another named inventor, stated during deposition that [REDACTED]

[REDACTED]. *See* Ex. E at 122:14-123:14. Dr. Lacroix, also an inventor, stated during deposition that [REDACTED]

[REDACTED]. *See* Ex. F at 151:14-17. Lastly, Mr. Wong, an inventor, [REDACTED]. *See* Ex. G at 81:14-82:12, 83:4-16, 85:10-16. Thus, none of the ’708 patent inventors can offer any evidence in support of Natera’s contentions regarding Owczarzy.

With no possible testimony from either its experts or inventors on Owczarzy, Natera cannot show that the UV and Primer3/SantaLucia methods do not result in significantly different primer melting temperatures. Natera’s theory regarding Owczarzy is unsupported.

d. Natera’s Remaining Arguments Further Confirm Indefiniteness

Natera’s remaining arguments fare no better than its Owczarzy theory. If anything, they just further prove indefiniteness.

As Defendants explained in their opening brief in support of their motion for summary judgment, the Primer3/SantaLucia method does not work for primers longer than 35 nucleotides. Natera never meaningfully denies this.⁴ The patent, meanwhile, repeatedly teaches that primers can be 100 nucleotides in length. *See, e.g.*, D.I. 433-2 at 19:14-17, 61:52-55. A question that begs to be answered, then, is what technique should be used for primers larger than 35 nucleotides?

Natera’s answer is that “a POSA would know to use the ultraviolet light method taught in the patent to measure the melting temperature of primers with more than 35 nucleotides.” D.I. 432 at 34-35. Natera itself, however, does not even agree with this. As Defendants explained in their opening brief in support of their motion for summary judgment, when confronted with a primer larger than 35 nucleotides during prosecution, Natera did not use the ultraviolet light

⁴ Nor could Natera deny this. The manual for the Primer3 version disclosed in the patent, along with the seven subsequent versions released prior to 2014, contain the same instruction to not use Primer3 for primers greater than 35 nucleotides in length:

PRIMER_MAX_SIZE (int; default 27)

Maximum acceptable length (in bases) of a primer. ***Currently this parameter cannot be larger than 35.*** This limit is governed by maximum oligo size for which primer3’s melting-temperature is valid.

D.I. 434, Ex. R at 21; Ex. H at 21; Ex. I at 21; Ex. J at 21; Ex. K at 21; Ex. L at 21; Ex. M at 21; Ex. N at 21.

method, but rather an undisclosed Bolton and McCarthy method. *See* D.I. 430 at 19-20. Nowhere did Natera suggest that the Bolton and McCarthy method was disclosed in the patent or that it produced results that were the same as the UV method. Natera’s assertion that a skilled artisan “would know” from the patent that the UV light method should be used for primers larger than 35 nucleotides is meaningless because Natera apparently did not even know this itself.

Natera also attempts to discount Dr. Cooper’s calculations proving that different melting temperature techniques yield very different results, arguing that “Defendants do not provide any evidence why a POSA would use these techniques [in a Chester paper] as opposed to the ultraviolet measurement taught in the patent.” D.I. 432 at 34; D.I. 419-10 ¶¶ 902-04. In fact, Defendants did provide such evidence. That evidence was Natera’s own statements to the Patent Office and public that one can use ***undisclosed*** methods such as Bolton and McCarthy to determine primer melting temperatures. Because Natera itself understood its patent claims to encompass the use of undisclosed methods such as Bolton and McCarthy, there is no reason to think a skilled artisan would not employ other methods, including the techniques proposed by Dr. Cooper.

Summary judgment of no indefiniteness is not warranted here.

2. “Sequencing Tag” Is Indefinite

Natera presents a cursory argument that the Court should grant summary judgment that “sequencing tag” is not indefinite. D.I. 432 at 35-36. Sidestepping the merits, Natera contends that the Court rejected indefiniteness during claim construction, such that summary judgment is warranted. The Court, however, only made an interim ruling that indefiniteness had not been proven at that early stage. The Court was clear that Defendants “will be permitted to attempt to prove its indefinite defense as this case proceeds.” D.I. 243 at 10.

Natera’s conclusory brief says nothing substantive to prove there is no remaining genuine issue of material fact on the indefiniteness issue. Natera asserts that “Defendants provide no

evidence that a POSA would not understand what a sequencing tag is with reasonable certainty as defined by the Court.” D.I. 432 at 36. In fact, Defendants’ expert, Dr. Cooper, presented extensive testimony on indefiniteness backed up by the following points and evidence:

- The term “sequencing tag” is a coined phrase with no prior definition in the art. D.I. 419-10 ¶ 890.
- There is no definition of “sequencing tag” anywhere in the patent. *Id.* ¶ 918.
- Every one of the very few references to “sequencing tag” in the patent fails to provide clarity as to its scope and simply creates confusion. *Id.* ¶¶ 918-23.
- The named inventors repeatedly testified that [REDACTED] *Id.* ¶¶ 924-926.
- Natera identifies numerous radically distinct DNA sequencing concepts (including “universal tags,” “molecular barcodes,” “sample indexes,” and “date tags”) as allegedly corresponding to a “sequencing tag,” thus further confusing the boundaries of the term. *Id.* ¶¶ 927-33.
- Natera’s own expert could not identify whether any of the sequencing concepts Natera identified could constitute a “sequencing tag” in its own right, further confirming that the term is not meaningful to those skilled in the art. *Id.* ¶¶ 932-33.

Natera ignores this and thus cannot show that there is no genuine issue of fact on indefiniteness.

Although the Court preliminarily construed “sequencing tag” to mean a “nucleic acid sequence introduced to carry out the process of high throughput sequencing,” this construction does not resolve the indefiniteness issue because there remains a fact issue as to whether skilled artisans understand what sequences are used to “carry out the process of high throughput sequencing.” This is borne out by evidence that has developed since claim construction.

Take, for instance, the issue of whether a “sequence tag,” can be a “sequencing tag.” A “sequence tag” is defined in the patent to be “a relatively short (e.g., 15-100) nucleic acid sequence that can be used to identify a certain larger sequence, e.g., be mapped to a chromosome or genomic

region or gene.” D.I. 438-1 at 187:20-24. Throughout the case, Natera has maintained that this can indeed be a “sequencing tag” by virtue of having some connection to high throughput sequencing, including through its claim construction expert, Dr. Quackenbush. *See, e.g.*, D.I. 178, Ex. A-2 ¶¶ 44-45, 48; D.I. 177 at 50-51. At the *Markman* hearing, for instance, Natera argued as follows:

THE COURT: How about sequence tag? How is that definition helpful to you?

A. Absolutely it’s helpful because it talks about it being an identifier. And that allows one – when multiple samples are pooled together for high throughput sequencing, in order to be able to make the high throughput sequencing meaningful and useful, you need to be able to understand what the identifier is. That small sequence does that. That could be, for example, the barcode that is used. *So sequence tag is actually in the context of this claim which is tied to high throughput sequencing.*

D.I. 185 at 109:4-15; *see also id.* at 75:22-76:14, 78:13-18.

After claim construction, however, Natera switched experts. Its new expert, Dr. Spellman, disagreed with the position Natera had taken throughout the case:

Q. “The term ‘sequence tag’ refers to a relatively short (e.g., 15-100) nucleic acid sequence that can be used to identify a certain larger sequence, e.g., be mapped to a chromosome or genomic region or gene.” Do you see that?

A. I do see the illustrative sequence tag.

Q. Okay. Let’s take a look at column 8, lines 57 to 61. It states: “A ‘sequence tag’ is a DNA sequence of sufficient length that it may be assigned specifically to one of chromosomes 1-22, X or Y.” Do you see that?

A. I – I do see that, yes.

Q. *Okay. Those references to sequence tag are not the same thing as the sequencing tag as used in Claim 1 of the '220 patent; correct?*

A. *I don’t believe that any person of ordinary skill in the art would believe that they’re the equivalent thing, no.*

Ex. BB at 250:19-251:13.

As another example, consider the concept of a “sample index,” which is a DNA sequence that can be appended to a DNA fragment to track which sample the fragment came from. Natera

has also consistently maintained that this can be a “sequencing tag.” Relying on Dr. Quackenbush, Natera urged at the *Markman* hearing that the “[e]xamples in the patent of sequencing tags that fall into the second bucket i.e., are necessary to allow the use of high throughput sequencing after multiplex PCR or after samples are [p]ooled are sample index or barcode.” D.I. 185 at 71:11-15; *see also* 77:14-23 (“It puts sample index as part of the broader concept necessary to facilitate sequencing on the high throughput sequencer.”); D.I. 178, Ex. A-1 ¶ 58; *id.*, Ex. A-2 ¶ 44.

Yet, at deposition, Natera’s new expert, Dr. Spellman, was clear that this sample-tracking function of a “sample index” does not correspond to the claimed “sequencing tag.”

Q Okay. Now, the traditional use of a sample index is simply to track which – which – which individual DNA fragment it came from; correct?

A. Correct. One wants -- on very high-throughput sequencing system, when you’re doing more sequencing than – than each individual requires, you want to put samples together and keep track of which – which DNA molecules came from which – which sample.

Q. Now, that – that use doesn’t make the sequencing happen; right?

A. ***I – I don’t think in that case, it – it would necessarily carry out the sequence.***

* * *

Q. Give me a scenario where a sample index would not be a sequencing tag, in your view. Can you do that?

A. I think I have given you that example. So if the – if the – if the sample tag is inside of all the other operational sequences, and the operational sequences used for carrying out sequences are 3' to that sample tag, then it would not qualify as a sequencing tag, in my mind.

Q. And why is that?

A. ***Because – because it’s not carry – it’s not a sequence used to carry out the sequencing.***

Ex. BB at 259:4-21, 261:15-262:3.

As the foregoing shows, the term “sequencing tag” is indefinite as a matter of law. At a minimum, there remains significant issues of fact as to whether the very things Natera points to as

being “sequencing tags” are truly the types of things used to carry out high throughput sequencing. Natera’s attorneys and its own expert witnesses cannot even agree on this factual issue, thus confirming that summary judgment is unwarranted.

B. Summary Judgment On Inventorship Is Unwarranted

Natera has maintained from the outset of this case that its alleged inventions pertain to breakthrough techniques for avoiding unwanted side products in multiplex PCR, in particular so-called “primer dimers.” *See* D.I. 430 at 3; D.I. 419-10 ¶¶ 754-756, 937-39. When it filed its patents in 2019 and 2020, Natera seemingly had a good understanding of who it believed solved this problem, naming a consistent group of ten individuals as inventors. Named inventor Zachary Demko, who is a patent agent and was in charge of Natera’s intellectual property function at the time of the alleged inventions, testified that [REDACTED].

Ex. P at 20:12-14, 105:10-107:7, 108:3- 109:15, 142:17-143:8.

Yet, in June 2021, nearly 18 months into this case, Natera filed petitions with the Patent Office to dramatically change inventorship on the ’814, ’482, ’172, and ’220 patents with a major reshuffling. For three of the patents, Natera sought to add Johan Baner, Milena Banjevic, Allison Ryan, and Zachary Demko as inventors and remove Joshua Babiarz, Tudor Constantin, Lane Eubank, Huseyin Kirkizlar, and Onur Sakarya as inventors.

It is no mystery why Natera made such drastic changes to its inventorship group. Several of the inventors that Natera originally listed on its patents (including Babiarz, Constantin, Eubank, Kirkizlar, and Sakarya) did not even work at Natera until long after the appearance of key prior art that Defendants identified after this case got started. By removing these individuals as inventors and adding individuals who were not, Natera sought to avoid any inference that its alleged invention post-dates the prior art relied upon in this case by Defendants.

Natera’s naming of a false inventorship group, however, renders its patents invalid under § 102(f). Given the circumstances here, the evidence of incorrect inventorship is overwhelming. Natera nonetheless now seeks summary judgment. Putting its head in the sand, Natera asserts that the only evidence of improper inventorship is uncorroborated inventor testimony. While there is surely ample inventor testimony, there is far more beyond this. Natera’s motion for summary judgment is misguided and should be denied.

1. Defendants’ Inventorship Defense Does Not Fail “As A Matter Of Law”

Natera argues as a threshold matter that Defendants’ inventorship defense fails “as a matter of law” because even if Natera named the wrong inventors it can correct inventorship pursuant to § 256. D.I. 432 at 22-23. To the extent Natera contends that invalidity for improper inventorship is legally unavailable as a defense, it is wrong.

Despite the fact that § 256 can be invoked to correct inventorship, a “party may raise the defense that a patent is invalid for failing to name the correct inventors.” *Drone Techs., Inc. v. Parrot S.A.*, 838 F.3d 1283, 1292–93 (Fed. Cir. 2016). Courts regularly find patents invalid for failure to name the proper inventors. *See, e.g., Bos. Sci. Corp. v. Johnson & Johnson*, 550 F. Supp. 2d 1102, 1114 (N.D. Cal. 2008) (“Because the jury found that Cordis proved by clear and convincing evidence that Byam was improperly named as a joint inventor of the Kastenhofer patents, the Court holds that, as a legal matter, the Kastenhofer patents are invalid under 35 U.S.C. § 102(f).”); *Plastipak Packaging, Inc. v. Premium Waters, Inc.*, No. 20-CV-098-WMC, 2021 WL 3675151, at *11–12 (W.D. Wis. Aug. 19, 2021) (granting summary judgment of invalidity under § 102(f) for failure to join proper inventors), *appeal filed*, No. 21-2244 (Fed. Cir. Aug. 25, 2021); *Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.*, No. CV 07-127-LPS-MPT, 2014 WL 547712, at *8 (D. Del. Feb. 7, 2014) (same); *Auxilium Pharms., Inc. v. Watson Labs., Inc.*, No.

CIV.A. 12-3084 JLL, 2014 WL 9859224, at *34 (D.N.J. Dec. 16, 2014) (concluding after bench trial that patent was invalid for failure to name proper inventors).

A “patent with improper inventorship does not avoid invalidation simply because it might be corrected under section 256. Rather, the patentee must claim entitlement to relief under the statute and the court must give the patentee an opportunity to correct the inventorship. If the inventorship is successfully corrected, section 102(f) will not render the patent invalid. On the other hand, if the patentee does not claim relief under the statute and a party asserting invalidity proves incorrect inventorship, the court should hold the patent invalid for failure to comply with section 102(f).” *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350–51 (Fed. Cir. 1998).

Thus, Defendants’ inventorship defense does not fail as a “matter of law” because Natera might invoke § 256. Rather, the inventorship defense must be presented to the jury and, if the defense succeeds, Natera can try to invoke § 256 “on notice and hearing of all parties concerned.” 35 U.S.C. § 256; *Pannu*, 155 F.3d at 1353 (“Iolab introduced sufficient evidence on which a reasonable jury could have found clear and convincing evidence that Link is a co-inventor. On such a finding and absent correction, the patent would be rendered invalid under section 102(f)”; *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 1512334, at *4 (E.D. Tex. Apr. 27, 2017) (“As occurred in the Cassidian Communications case, the defendants could win on their inventorship defense, but Allergan could move to correct inventorship under section 256 and, if prevailing on that motion, move to vacate the judgment of invalidity.”); *Genifuel Corp. v. Oyler*, No. 2:11-CV-838 TS, 2012 WL 1032782, at *3 (D. Utah Mar. 27, 2012) (describing the procedure a court must follow when faced with an inventorship defense).

In the event Natera “failed to seek, or obtain, correction of inventorship” following a finding of improper inventorship, however, its patents would be rendered permanently invalid.

Allergan, 2017 WL 1512334 at *4. Although Natera suggests that it will have little trouble correcting inventorship if the jury finds that its patents name the wrong inventors, this is not so. Natera has already changed inventorship once before. *See* D.I. 432 at 6. Natera did so because its patents listed as inventors several individuals who did not work at Natera until long after Natera’s desired priority date and invalidating prior art had appeared. By removing these individuals as inventors and adding individuals who worked at Natera in an earlier time frame, Natera sought to avoid any inference that its alleged invention post-dates the prior art.

If faced with a jury verdict of improper of inventorship, however, Natera will face a dilemma: correcting inventorship again will simply give rise to the inference of invalidity Natera originally sought to avoid. What’s more, given that Natera already changed inventorship to support its litigation positions, judicial estoppel may well preclude Natera from making yet another round of inventorship changes even if it wants to. While the possibility of Natera correcting inventorship pursuant to § 256 does not prevent Defendants from presenting their inventorship defense under any circumstances, there is little reason to believe that Natera would even be able to invoke § 256 to save its patent following an improper inventorship verdict.

2. There Are Genuine Issues Of Fact On Inventorship

Evaluating joint inventorship is a fact-intensive exercise and “one of the muddiest concepts in the muddy metaphysics of patent law.” *In re VerHoef*, 888 F.3d 1362, 1365 (Fed. Cir. 2018) (citation omitted). “The determination of whether a person is a joint inventor is *fact specific*, and no bright-line standard will suffice in every case.” *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997).

Given the fact-intensive, muddy nature of inventorship, summary judgment should be rarely granted. *See F'Real Foods, LLC v. Hamilton Beach Brands, Inc.*, No. 16-41-CFC, 2019 WL 1747550, at *1 (D. Del. Apr. 18, 2019), aff’d, 854 F. App’x 379 (Fed. Cir. 2021) (denying

summary judgment where inventorship dispute was based on a single document); *E.I. DuPont De Nemours & Co. v. Unifrax I, LLC*, No. 14-1250-RGA, 2017 WL 1822279, at *3 (D. Del. May 5, 2017) (denying summary judgment where disputes existed concerning an alleged co-inventor’s contribution to the invention); *Institut Pasteur v. Simon*, 384 F. Supp. 2d 802, 805 (E.D. Pa. 2005) (“It is enough that the parties’ submissions on this issue indicate the existence of disputed facts that go directly to the heart of [the] claims of inventorship.”).

Natera nonetheless contends that Defendants “have not sustained” their burden to prove improper inventorship, ostensibly due to a lack of corroborating evidence. D.I. 432 at 24. Natera, however, misunderstands the standard on summary judgment, presenting nothing in its brief to establish that there are no genuine issues of material fact on the inventorship issue. Natera points to signed statements from the alleged inventors that it submitted in June 2021—nearly 18 months into the case—attesting to the veracity of Natera’s preferred inventorship group. See D.I. 432 at 6. Yet, not one of these individuals was able to explain their attestations to this effect. See Ex. Q at 48:9-49:10; Ex. R at 114:10-115:4; Ex. S at 116:8-118:23; Ex. P at 163:12-165:6; Ex. T at 66:12-67:4; Ex. U at 133:17-134:4; Ex. E at 246:11-247:24; Ex. V at 103:9-22; Ex. C at 239:6-240:1; Ex. W at 111:15-113:19; Ex. X at 134:21-135:8. This alone should defeat summary judgment.

As documented below, the evidence showing that Natera named the wrong inventors on its patents is overwhelming.

a. There Are Genuine Issues Of Material Fact As To Whether Natera Omitted Inventors

As to the omission of inventors, Natera’s brief reads as if there is no evidence beyond uncorroborated inventor testimony. While there is undoubtedly inventor testimony, there is much more. Natera’s motion is based on willful blindness to this evidence.

Take, for instance, the case of Phillippe Lacroute, who Natera mentions only once in its brief.⁵ As Defendants' expert explained, Dr. Lacroute testified that [REDACTED]

[REDACTED]. See D.I. 419-10 ¶¶ 945-47. Specifically, he identified [REDACTED]
[REDACTED]
[REDACTED]. See *id.*; D.I. 391-2, Ex. 5 at 48:4-50:18.

Natera cannot deny that this exact thing corresponds to its alleged invention. Throughout the case, Natera has asserted that its alleged inventions pertain to avoidance of primer dimer side products. See D.I. 430 at 3; D.I. 419-10 ¶¶ 754-756, 937-39. When Natera's technical expert, Dr. Quackenbush, was asked to identify the techniques used in the "claimed invention" of the '220 patent for this purpose, he identified the exact thing that Mr. Lacroute developed:

And again, one skilled in the art would understand that the patent in its specification itself instructs us to use primer 3. Primer 3 is a technology or is a primer design tool that, in fact, was constructed to avoid the formation of primer dimers, right?

So one skilled in the art would understand that the at least ten target loci would be amplified by target specific primers that would avoid the formation of primer dimers, right?

* * *

So again, one skilled in the art would understand that in doing this nested PCR, one would design those primers as instructed by the written description using a tool such as Primer3, which is what the patent teaches us to use, and to do that in a way to avoid the formation of primer dimers.

⁵ Given the extent of the changes Natera made to its inventorship group, it is not possible for Defendants to address every inventor in this brief, and Defendants have thus focused on Phillippe Lacroute on the issue of non-joinder. Yet, corroborated evidence exists for other non-joined inventors as well, showing their role in addressing primer dimers in multiplex PCR and other specific work on multiplex PCR. This includes publications by Natera scientists, the resume of a Natera inventor, and internal email correspondence. See, e.g., Ex. Y; Ex. Z; Ex. AA; Ex. UU.

D.I. 434, Ex. L at 150:4-13; 150:25-151:5. When confronted with this testimony in light of what Dr. Lacroute contributed to the patents, Natera’s expert on inventorship, Dr. Spellman, dissembled:

Q. Okay. So you would agree on that basis that unless Dr. Lacroute is lying about what he actually did during his time at Natera, he should be named as an inventor on the ’220 patent; correct?

A. Yeah, I – I’d have to go through – I’d have to go through the inventorship rules about that I don’t know that that’s quite the way it works.

Ex. BB at 243:10-19.

Natera never attempts to explain why Dr. Lacroute is not an inventor. Sidestepping any merits-based discussion of what he (or any other inventor) actually worked on, Natera at most contends generally that there is no corroborated evidence on inventorship. *See* D.I. 432 at 24. Natera is wrong.

Natera’s own patent filings corroborate Dr. Lacroute’s testimony. The very technique in Natera’s patents for primer design based on the use of Primer3 to compute “undesirability scores” first appeared in Natera’s patent filings in a November 21, 2012 patent application entitled “Highly Multiplex PCR Methods And Compositions.” *See* Ex. CC ¶¶ 185-86. This was *after* Dr. Lacroute started working at Natera in early spring 2012. *See* Ex. F at 20:14-21:11. Unsurprisingly, Dr. Lacroute is an inventor on this application. *See* Ex. CC at (72). What’s more, each of Natera’s ’220, ’172, and ’814 patents claim the benefit of this application. Prior to Dr. Lacroute, none of Natera’s patent filings included the primer design method based on Primer3 and “undesirability” scores. Thus, by its own patent filings, Natera corroborates Dr. Lacroute’s testimony and effectively admits that he should be an inventor.

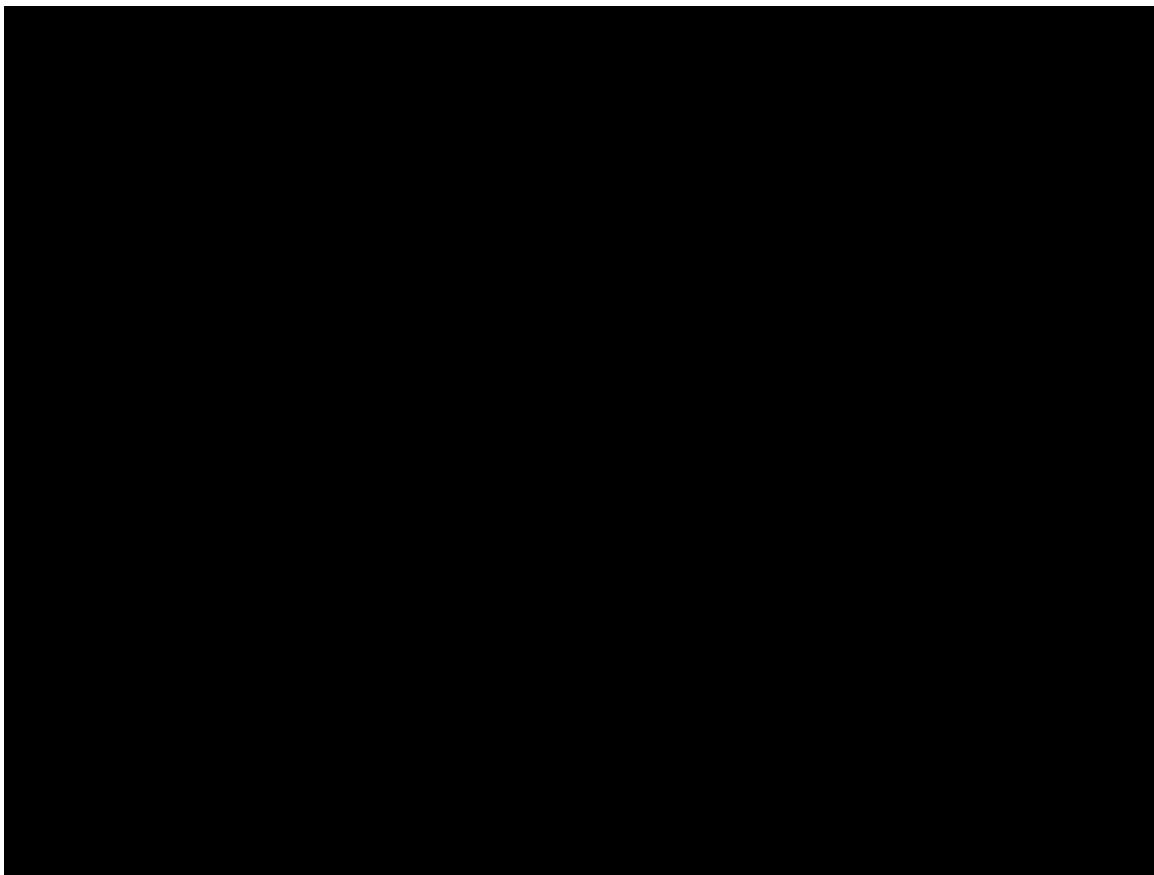
Natera’s internal documents also corroborate Dr. Lacroute’s testimony. Natera touts its “approximately 100-page long” interrogatory response as supposedly backing up its inventorship story. The documents in Natera’s interrogatory response, however, simply corroborate Dr.

Lacroute's contribution. According to Natera, prior to April 2013, Dr. Lacroute [REDACTED]

[REDACTED] D.I. 433-3, Ex. 21 at 422. Natera cites documents authored by Dr.

Lacroute that [REDACTED]

[REDACTED] :

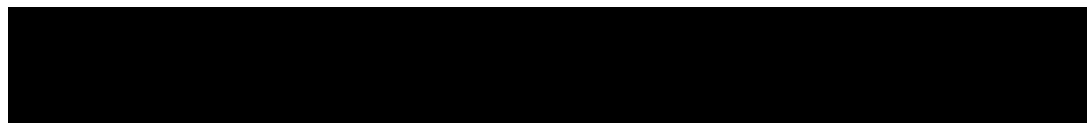


Ex. DD at 4, 7-8. Additional internal email correspondence within Natera further confirms that

[REDACTED]. *See, e.g.*, Exs.

FF-HH.

Finally, yet additional corroborating testimony comes from other Natera witnesses, including both inventors and non-inventors, who confirmed that Dr. Lacroute worked on the primer design problem while at Natera:





Ex. D at 41:6-21; *see also* Ex. E at 137:15-25; Ex. G at 53:8-14. Given the foregoing corroborated evidence, there is at least a genuine issue of material fact as to whether Natera omitted inventors on its patents.

b. There Are Genuine Issues Of Material Fact As To Whether Natera Joined The Wrong Inventors

Just as Natera omitted inventors from its patents to prevent an inference that it did not make its alleged inventions until it was too late, it also added several inventors (Gemelos, Ryan, Banjevic, and Demko) to bolster the notion that it made its inventions earlier than it really did. While these inventors submitted affidavits to the Patent Office in support of the change, at deposition they had no clue what they might have done to justify being named as inventors. *See, e.g.*, Ex. U at 85:16-86:15; Ex. W at 72:11-73:4, 73:13-74:14, 74:18-76:4; Ex. R at 83:5-84:6, 86:12-19, 87:9-88:4, 105:25-106:21; Ex. P at 104:17-105:12. This alone raises an issue of material fact that precludes summary judgment.

In fact, it is clear that these inventors did nothing whatsoever related to the development of multiplex PCR techniques. Dr. Allison Ryan, for instance, is [REDACTED]

[REDACTED]. Ex. W at [REDACTED]

[REDACTED]

[REDACTED]. Dr. Ryan further testified that [REDACTED]

[REDACTED]. *See id.* at 30:12-20, 65:23-66:14, 68:11-14.

Like Dr. Ryan, Dr. Gemelos [REDACTED]

[REDACTED] . Ex.

U at 17:24-18:4, 41:3-20, 45:3-20, 53:15-24, 55:9-15, 58:16-59:10, 60:10-20. Dr. Banjevic's testimony [REDACTED] . See Ex. R at 15:12-18, 17:24-20:25, 74:14-75:9. A reasonable juror could easily find based on such evidence alone that Natera's alleged inventors could not possibly have played a bona fide role in helping to conceive new of multiplex PCR techniques.

Natera nonetheless points to its "approximately 100-page long" interrogatory response, alleging that "Defendants have no response to this evidence." D.I. 432 at 25-26. Consistent with the alleged inventors' total lack of any basic understanding of PCR, Natera's cited documents confirm only that they must have worked on things *other than* the PCR concepts in the claims. Consider, for example, some of the documents Natera cites as showing the alleged contributions of Ryan, Banjevic, and Gemelos and Dr. Ryan's testimony about these documents:

- Natera points to a document related to [REDACTED] D.I. 433-3, Ex. 21 at 332. Dr. Ryan testified that [REDACTED] [REDACTED] Ex. W at 41:9-42:5. When asked if the document related to development of multiplex PCR methods, [REDACTED] . *Id.* at 41:22-25. On its face, the document is irrelevant.
- Natera points to a document regarding [REDACTED] D.I. 433-3, Ex. 21 at 352. Dr. Ryan testified that [REDACTED] [REDACTED] Ex. W at 43:8-44:2. When asked about whether [REDACTED] [REDACTED] *Id.* at 81:7-16.
- Natera points to a document that [REDACTED] D.I. 433-3, Ex. 21 at 352. Dr. Ryan [REDACTED] . Ex. W at 44:24-

45:12. The document [REDACTED]

Id. at 45:20-46:3.

- Natera points to a document about [REDACTED] D.I. 433-3, Ex. 21 at 353. Dr. Ryan [REDACTED] Ex. W at 48:5-49:1
- Natera points to a document about [REDACTED] D.I. 433-3, Ex. 21 at 353. Dr. Ryan said [REDACTED]
[REDACTED] Ex. W at 50:10-17.

Following trial, a reasonable jury could easily conclude solely from Natera’s own documents and related testimony that Natera named the wrong inventors on its patents. While Natera boasts that its interrogatory response cites “nearly 300 corroborating documents,” it tellingly does not discuss a single one of them in its brief. *See* D.I. 432 at 25. Natera is not entitled to a summary judgment simply because it has cited a truckload of documents that it never discusses in any detail. If anything, Natera’s resort to a strategy based on volume over substance confirms that summary judgment is unwarranted.

3. Natera’s Remaining Arguments Are Irrelevant And Logically Flawed

What remaining arguments Natera presents suffer from fundamental logical flaws and do not establish that Natera is entitled to summary judgement. Natera points out that the “removed inventors joined Natera after the filing of the priority ‘235 application in November 2011.’” D.I. 432 at 26. According to Natera, an “employee who joined Natera after the conception of the invention and the filing of a patent application disclosing the invention could not have contributed to the conception of that invention.” *Id.*

This argument, however, assumes that everyone agrees Natera made its invention in November 2011. In fact, Defendants dispute this, and have submitted detailed expert witness testimony rebutting Natera’s priority date and are seeking summary judgment on the issue. *See*

D.I. 419-10 ¶¶ 50-67; D.I. 430 at 29-36. If Natera invented anything, it was not until long after November 2011, and Natera’s unsupported assertions about its preferred priority date do not entitle it to summary judgment.

Finally, Natera asserts that summary judgment is warranted because Defendants’ expert, Dr. Cooper, “admitted that he only evaluated the patents and select testimony excerpts of the omitted inventors.” D.I. 432 at 25. Apparently, Natera believes Defendants’ expert did not present all of the evidence needed for Defendants to prevail on the inventorship issue. Even if true, however, Natera’s argument assumes that Defendants will present evidence on inventorship solely through expert witness testimony. While Defendants certainly will present expert witness testimony, as documented above, there will be additional evidence in the form of Natera’s own documents, patent filings, and fact witness testimony. Any one of these forms of evidence establishes that there is at least a genuine issue of material fact on the inventorship issue.

C. Summary Judgment on Inequitable Conduct Is Unwarranted

As explained above, Natera filed petitions with the Patent Office—nearly 18 months into this case—to revamp the group of named inventors on the ’814, ’482, ’172, and ’220 patents. This was done to avoid the implication that the alleged inventions occurred after the prior art identified by Defendants, including work done by researchers at Massachusetts General Hospital who, unlike Natera’s inventors, developed and patented the technology used in the Accused Products. Because inventorship is fundamentally material to patentability (*see* 35 U.S.C. §§ 101, 102(f)), and, at minimum, a reasonable fact finder could conclude that Natera intended to deceive the Patent Office, Natera’s motion for Summary Judgment should be denied.

Further, during prosecution of the ’220 Patent, Natera failed to disclose briefing and pleadings explaining how key claim elements of the ’814 patent (which are shared with the ’220 patent) are in the prior art and how the ’814 patent failed to meet the requirements of § 112. These

undisclosed documents identify *Natera's own statements* in other litigations describing claim elements as routine and conventional. Natera cannot dispute that it was aware of its duty to disclose these documents because it disclosed other litigation documents, albeit documents that were less likely to harm its chances of getting a patent. Dr. Rabinowitz, the Executive Chairman of Natera, [REDACTED].

Had this inequitable conduct not occurred, the '220 patent would not have issued.

1. Natera's "Correction" of Inventorship Was Inequitable Conduct

a. Inventorship Is Material

Natera argues that Defendants have failed to establish that its incorrect identification of inventors is "material to the issuance of any of the patents at issue." D.I. 432 at 15. Yet, as "a critical requirement for obtaining a patent, inventorship is material." *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 830 (Fed. Cir. 2010) (citing *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000)). Natera's misrepresentation of the alleged inventors of the patents-in-suit would clearly result in the patents being held invalid. 35 U.S.C. § 102(f) (pre-AIA) ("A person shall be entitled to a patent unless...he did not himself invent the subject matter sought to be patented."); *see also* 35 U.S.C. § 101; *In re VerHoef*, 888 F.3d at 1368 (affirming rejection of claims for improper inventorship under § 102(f)).

In fact, when it comes to inventorship, the Federal Circuit has been clear that it "is the inequitable-conduct rules that provide a safety valve in the event of deceit." *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1377 (Fed. Cir. 2020). Natera's contention that inequitable conduct for naming improper inventors is not legally cognizable is irreconcilable with the Federal Circuit's guidance that this provide a "safety valve" in the event of deceit.

b. There Is More Than Sufficient Evidence To Conclude That Natera’s Inventorship “Correction” Was Intended To Deceive

Natera applies the incorrect standard for summary judgment. To defeat summary judgment, Defendants need only show that a reasonable fact finder could, viewing facts in the light most favorable to defendants, conclude that the single most reasonable inference to be drawn was that Natera had a specific intent to deceive the Patent Office, not that it is the only possible inference. *Transcend Med., Inc. v. Glaukos Corp.*, 2015 WL 5546986, at *7 (D. Del. Sept. 18, 2015). As shown above, there is overwhelming and unambiguous evidence that Natera “corrected” its patents to name the wrong inventors, including people who had no idea how PCR works and omitting people who had key roles developing the techniques Natera’s own experts identified as key to practicing the invention. *See supra* Part II.B.2. Given nothing more than this extreme disconnect between the evidence (which Natera was undoubtedly aware of) and Natera’s proposed inventorship group, a reasonable jury could easily conclude that Natera acted with intent to deceive.

Natera nonetheless points to its inventor declarations as somehow proving that its correction of inventorship was proper. D.I. 432 at 17. If declarations from inventors were all that were required to rebut inequitable conduct allegations, however, inequitable conduct would be eviscerated as all inventors submit such declarations when filing patents. Here, as explained above, none of the inventors could explain their attestations for Natera’s preferred listing of inventors. *See supra* Part II.B.2; *see also F’Real Foods*, 2019 WL 1747550, at *1 (finding jury could reasonably conclude that improper inventorship assertions “were materially and intentionally misleading, amounting to inequitable conduct”). This total inability of every one of Natera’s “inventors” to justify their inventorship oaths, at minimum, creates a genuine issue of material fact as to intent.

The cases cited by Natera are inapposite. Each involve situations where the inventors explained their rationale for changing their position and did not involve the wholesale swapping of groups of individuals, as is the case here. *See Dealertrack Inc. v. Huber*, No. 06-cv-2335, 2008 WL 11337833 (C.D. Cal. July 21, 2008), at *3 (removed inventor explaining that claims did not involve the graphic user interface that she was involved with); *Dexcowin Global Inc. v. Aribex Inc.*, No. 16-cv-143, 2017 WL 3477748 (C.D. Cal. June 7, 2017) (added inventor was 12-years-old at the time and did not believe he was an inventor). Natera's witnesses, by contrast, had no explanation for the change in inventorship. As such, the unexplained and unjustified oaths that Natera now relies upon are, if anything, just further evidence of deceit before the Patent Office.

Consider, for instance, Zachary Demko, one of Natera's late-added inventors. He [REDACTED]

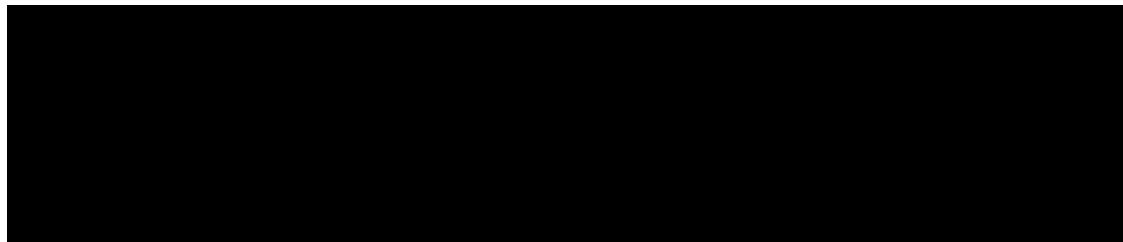
[REDACTED]
[REDACTED]. But he had no justification for signing his oath to change inventorship:

[REDACTED]



Ex. P at 163:12-165:6. If Dr. Demko cannot give a substantive explanation for why he signed his affidavit to correct inventorship, nobody at Natera can.

Indeed, across the board, Natera invoked the attorney-client privilege to *conceal* any explanation for its changes in inventorship. The testimony of removed inventor Lane Eubank is illustrative of every individual who submitted one of Natera's oaths to correct inventorship:



Ex. T at 66:12-67:4 *see also* Ex. Q at 48:9-49:10; Ex. R at 114:10-115:4; Ex. S at 116:8-118:23; Ex. U at 133:17-134:4; Ex. E at 246:11-247:24; Ex. V at 103:9-22; Ex. C at 239:6-240:1; Ex. W at 111:15-113:19; Ex. X at 134:21-135:8.

This is the exact opposite of a situation where the credible explanation of an inventor can diffuse allegations of intent to deceive the Patent Office. If anything, Natera's dubious invocation of privilege to conceal factual information about why so many people agreed to change their inventorship status reinforces intent to deceive.

2. Natera's Withholding Of Material Litigation Documents Is Inequitable Conduct

Dr. Matthew Rabinowitz is the Executive Chairman, founder, and former-CEO of Natera, as well as a named inventor on the '220 Patent. It is undisputed that in his role and as an inventor of the '220 patent he was aware of this litigation.

Yet, despite having litigation documents from Defendants explaining how a related patent with similar subject matter (the '814 patent) was invalid under §§ 101, 103, and 112, including specific citations to *Natera's own statements* about what was "routine" and "conventional" prior to the earliest possible priority date for the '220 patent, Dr. Rabinowitz and Natera failed to provide them to the Patent Office. Natera disclosed other documents from these same litigations and as such cannot claim that these type of documents cannot be material. This selective disclosure by Natera and Dr. Rabinowitz is more than sufficient for a reasonable jury to conclude that there was intent to deceive.

a. The '220 Patent Would Not Have Issued If Natera Had Disclosed The Litigation Documents

ArcherDX's Answer and Answer to FAC, which Natera did not disclose to the Patent Office, explained that the '814 Patent, which claims highly similar methods to the '220 Patent, is invalid under § 103. D.I. 14, 21. For example, these documents explained that the prior art of Mir alone or Mir in a specific combination with Wang, Spertini, or Makarov, discloses all elements of the '814 Patent claims. Natera contends that this detailed explanation of invalidity is not material because the individual references were before the examiner. Natera's contention that the individual ingredients of an obviousness theory are material and should be disclosed while the fully-assembled obviousness theory is not material makes little sense and is unsupported.

Moreover, Natera admitted in its answer to ArcherDX's inequitable conduct counterclaims that the individual references were buried among thousands of other references. D.I. 393 at 136

¶ 133 (“Natera disclosed Mir, Wang, Spertini, and Makarov as four of thousands of references during prosecution of the ‘220 Patent.”). This type of buried disclosure does not make Natera immune from inequitable conduct.

Like ArcherDX’s Answer and Answer to FAC, Archer’s 12(c) motion was also not submitted to the Patent Office. D.I. 24. This document includes an easy-to-follow table highlighting *Natera’s own admissions* that elements of the ’814 patent, which correspond to elements of the ’220 patent, are routine or conventional. *Id.* at 16–17. It is inexplicable that Natera failed to disclose this validity-destroying record of its own admissions regarding what is allegedly routine and conventional.

Had Natera disclosed these documents, the Patent Office would have had an easy to follow roadmap laying out the why the ’220 patent is invalid. A reasonable jury could easily conclude from this that the ’220 patent is invalid and should not have issued. Natera insinuates that such briefs and litigation documents can never be material to patentability. Courts, however, have regularly found that such documents are material and should be disclosed to the Patent Office. *See, e.g., Therasense, Inc. v. Becton, Dickinson & Co.*, 864 F. Supp. 2d 856, 860 (N.D. Cal. 2012) (finding on remand that withheld EPO briefs were but-for material to patentability).

b. There Is More Than Sufficient Evidence To Conclude That Natera’s Withholding Of Litigation Documents Was Intended To Deceive

The fact that Natera and Dr. Rabinowitz cherry-picked litigation documents to provide to the Patent Office, while omitting key documents that spell out precisely why the ’220 patent should not have issued, is more than sufficient for a jury to conclude that Dr. Rabinowitz was intending to deceive.

Natera cites *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009), for the proposition that intent to deceive cannot be inferred solely based on the fact that

Natera had some level of knowledge about the withheld references. In *Exergen*, however, the only fact was that the applicant disclosed the reference in one application, but did not disclose it during prosecution of a related application. Here, there is no question, and no dispute by Natera, that the '814 patent is related to the '220 patent and that arguments regarding the former could apply to the later. Further, these litigation documents are not simply references among many, like in *Exergen*, but rather a detailed description of why the '814 Patent is invalid under §§ 101, 103, 112. It is more than reasonable to conclude that Dr. Rabinowitz was aware of these arguments yet chose to keep them from the Patent Office.

Because there is at least a genuine issue of material fact as to evidence of materiality and intent, Natera's motion should be denied.

D. Natera Is Not Entitled To Summary Judgment That The Inventors Claimed What They Regarded As Their Invention Under § 112

Natera contends that there is "simply no evidence that the patentee did not regard the claimed methods as its inventions." D.I. 432 at 28. This is more willful blindness to the evidence. It cannot be disputed that Natera did not claim what its inventors regarded as their invention and that its claims are invalid under the Federal Circuit's *Allen Engineering* case.

It is unsurprising that this is so. As Defendants explained in their opening brief in support of their motion for summary judgment, Natera drafted its 200-column specifications nearly a decade ago. D.I. 430 at 32. Yet, as Natera's Executive Chairman and named inventor confirmed, Natera never even began drafting the claims until 2019, after the release of certain of Defendants' products prompted Natera to do so. Ex. II at 331:21-332:14, 392:2-9, 441:6-13. The late drafting of claims as part of an effort to capture a competitor's products decades after inventors made their alleged inventions are classic conditions where a company will be tempted to stretch its claims beyond what inventors truly regarded as their invention. That happened here.

1. Natera's Claims Do Not Address The Primer Dimer Problem In Multiplex PCR

Natera has been clear throughout this case that its alleged inventions pertain to techniques for avoiding primer dimers. *See* D.I. 430 at 3; D.I. 419-10 ¶¶ 754-756, 937-39. Natera even put this in its complaint:

The patent specification explains that sequencing was problematic after multiplex PCR because of artifacts such as primer-dimers formed during the amplification process, skilled artisans were therefore using methods such as microarrays instead of sequencing, *and now that the patent teaches a way to minimize the formation of primer-dimer artifacts, multiplex PCR followed by sequencing could be done more effectively.*

D.I. 391 ¶ 72.

One would expect, then, that the claims would have some features that actually allowed one to minimize primer dimers. Yet, the lead inventor who oversaw Natera's multiplex PCR development, Dr. Bernhard Zimmerman, [REDACTED]:

[REDACTED]

Ex. B at 226:3-9; *see also id.* at 248:3-249:1 [REDACTED]

[REDACTED]

[REDACTED]

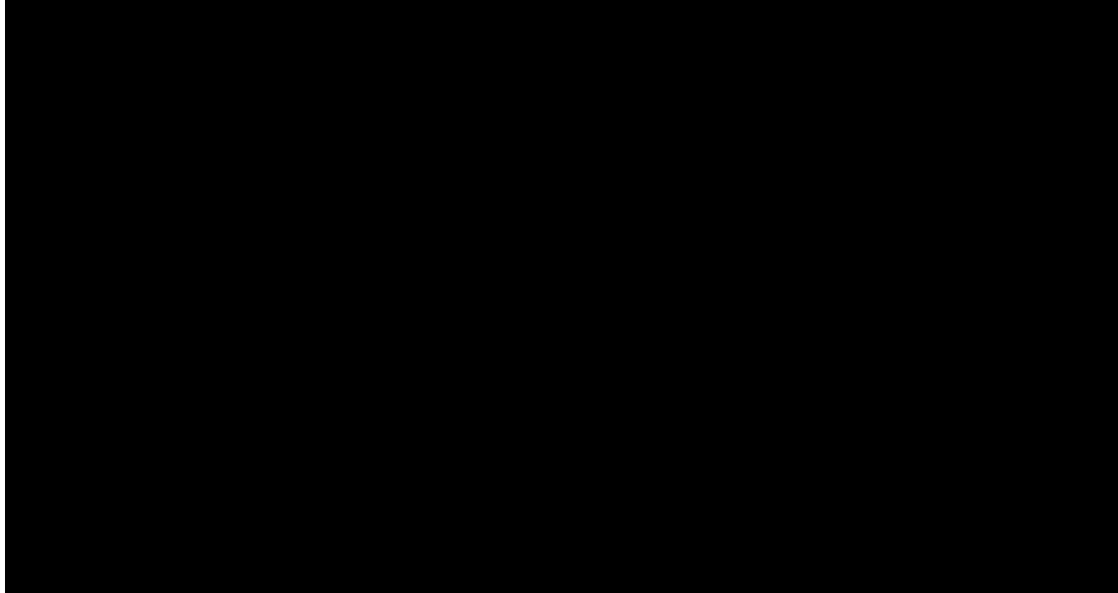
[REDACTED].

According to Dr. Zimmerman, the claims [REDACTED]

[REDACTED]

[REDACTED]:

[REDACTED]



Id. at 233:19-235:3. To the extent Natera regards its invention as something that avoids the primer dimer problem and enables multiplex PCR, that invention is not part of the claims as drafted. This alone proves that there remains a genuine issue of material fact on that dispute.

Natera nonetheless contends that there can be no invalidity under *Allen Engineering* because there is no “indefiniteness” unless there is an “irreconcilable contradiction” between the patent specification and claims. D.I. 432 at 28. Natera misunderstands both the law and Defendants’ invalidity theory. For “a claim to comply with section 112, paragraph 2, it must satisfy two requirements: first, it must set forth what ‘the applicant regards as his invention,’ and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently ‘definite.’” *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377 (Fed. Cir. 2000); *see also Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002) (explaining that § 112 includes two requirements, one for definiteness and one that the inventors claim what they regard as their invention). Defendants’ invalidity theory is not based on indefiniteness, but the distinct requirement that inventors claim what they regard as their invention. No law establishes that this basis for invalidity requires an “irreconcilable contradiction.”

Even if there were such a requirement, an “irreconcilable contradiction” is present here. Natera scientists did indeed work on the problem of avoiding primer dimers. As Defendants’ expert explains in great detail through citation to copious record evidence, the solution they allegedly came up with was novel techniques of selecting primers so as to avoid primer dimers. D.I. 419-10 ¶¶ 758-68, 770, 832-36, 850-52. The patent states that this is “essential” for high multiplex PCR:

At high multiplexing it is not possible to eliminate all spurious interactions, but it is **essential** to remove the primers or pairs of primers with the highest interaction scores in silico as they can dominate an entire reaction, greatly limiting amplification from intended targets.

D.I. 78-1, Ex. 5 at 54:46-50; *see also id.* at 3:4-9; D.I. 419-10 ¶ 770.

Yet, this “essential” concept is not in the claims. Based on overwhelming evidence in the specification, Defendants argued during claim construction that the claims should be construed to require “primers with sequences complementary to the nucleic acid **selected to avoid primer side products.**” *See, e.g.*, D.I. 177 at 13-17. Natera opposed this, arguing that the claimed inventions “avoid the use of primer dimer side products, but it’s not through selection of the target loci and it’s not through selection of the primers themselves.” D.I. 185 at 34:9-18; *see also id.* at 6:3-10, 6:19-7:2, 12:12-22. The Court adopted Natera’s position as a matter of claim construction based on the claim text. D.I. 243 at 6.

Thus, the claims as construed by the Court include no constraints whatsoever on the selection of primers to avoid side products. That is, the claims do not include the “essential” thing that the specification makes clear the inventors regarded as their invention. This is an irreconcilable contradiction between the specification and claims, which Natera ignores in its brief. Natera’s failure to address this again proves that there is an outstanding issue of material fact.

2. The Inventors Did Not Regard Nested PCR As Their Invention

Unable to contend that the claims recite the “essential” primer selection techniques that the specification makes clear the inventors regarded as their invention, Natera argues that the specification “teaches the claimed multiplex nested PCR methods as one way to combat the off-target amplification caused by primer dimers.” D.I. 432 at 27. This contention that “nested PCR” is what the inventors regarded as their invention is without merit.

As Dr. Cooper explained in his report by citation to inventor testimony and prior art literature, Natera did not invent nested PCR. D.I. 419-10 ¶¶ 155-63. Natera’s lead inventor, Dr. Zimmerman, agreed:



Ex. B at 97:11-98:15.

Natera’s invalidity expert, Dr. Spellman, likewise agreed with Drs. Cooper and Zimmerman that Natera did not invent nested PCR:

Q. You don’t – you don’t dispute that nested PCR was known in the art prior to the 2011 time frame; correct?

A. I do not dispute that.

Ex. BB at 77:1-7; *see also id.* at 128:6-9 (confirming that one-sided nested PCR is prior art); *id.* at 144:7-11 (one-sidedness and nesting was known in the art). Thus, Natera cannot possibly contend that its inventors regarded nested PCR as their invention because everyone from Natera agrees that they did not invent this.

Natera nonetheless contends that the patent teaches that nested PCR is the invention, relying on nothing more than two terse passages in the 200 column specification of the '220 patent, unsupported by any expert testimony. First, Natera points to the passage at 86:29-47. This, however, merely describes an approach to "divide the sample up into multiple multiplexed target enrichment reactions with more moderate numbers of target sequences per reaction." D.I. 438-1 at 86:26-29. This is the exact opposite of the claims, which requires performing the PCR reactions "in a single reaction volume." Moreover, the passage never mentions nested PCR, except briefly at the end to suggest that one could use it "in an embodiment." *Id.* at 86:45-49. Far from describing nested PCR as inventive, the patent suggests the exact opposite by giving it cursory treatment on the assumption it was well-known to the skilled artisan, as Natera's inventors and experts all agree.

Second, Natera points to a passage at 98:9-36, which describes Figure 6 of the patent. This, however, is just a description of one-sided nested PCR. *See id.* at 98:9; *see also* D.I. 433-3 ¶ 14 (explaining that the disclosure cited by Natera is "prior art one-sided semi-nested PCR."); Ex. JJ at 120:4-15. As noted above, Natera's own expert confirmed that one-sided nested PCR is not Natera's invention, but rather a known prior art concept. *See* Ex. BB at 128:6-9, 144:7-11. Natera's inventor and executive chairman, Matthew Rabinowitz, likewise testified as follows:

[REDACTED]

Ex. C at 254:6-255:17.

Lacking any good evidence in the specification that describes nested PCR as the invention, Natera contends that Defendants' expert, Dr. Cooper, admits "the claims match the express disclosure in the specification." D.I. 432 at 29. It likewise points to testimony from Dr. Cooper that the patent never explicitly states that nested PCR is *not* the invention. *Id.* at 28. This is all hollow. Dr. Cooper's testimony about the claims allegedly matching the disclosure in the specification was nothing more than confirmation that the both the specification and claims describe *prior art* one-sided nested PCR. *See* Ex. LL at 254:2-6 ("Q. So Figure 6 is a representation of a one-sided nested PCR, correct? A. Right. I think so. I think it would take me a while to fully understand all the details here, but yes, I believe that's true.").

Likewise, Dr. Cooper's testimony that there is nothing in the patent affirmatively stating that nested PCR is "not" an invention proves nothing. Natera's reliance on this testimony is premised on the erroneous assumption that patentees explicitly label certain passages of their patents as "not an invention." As Dr. Cooper, stated, "I don't know why an inventor would literally write that into their patent, but I don't see it, any literal phrase that says, quote-unquote, 'not an invention.'" *Id.* at 404:15-18.

Natera is not entitled to summary judgment that the patentees claimed what they regarded as their invention. The evidence, in fact, points uniformly to the opposite conclusion.

E. Natera Is Not Entitled To Summary Judgment Of No Prosecution Laches

Defendants contend that Natera delayed nearly a decade in presenting its claims for prosecution, which, in view of the totality of the circumstances, was unreasonable. Natera was monitoring ArcherDX's products for infringement as early as 2014. Natera considered

ArcherDX a competitor in the oncology space as early as 2016. Yet, Natera chose not to file its patents until it started losing business to ArcherDX in 2019. Defendants' positions on these factual issues, along with every other aspect of Defendants prosecution laches defense, are supported by detailed and thorough expert witness testimony from Defendants' expert, Nathan Kelly, whose opinions are based on his experience as Solicitor and Deputy General Counsel for Intellectual Property Law at the United States Patent Office. *See generally* D.I. 433-3, Ex. 24. As documented below, given the outstanding factual issues and the expert testimony, summary judgment is not remotely warranted.

1. Natera's Delay Was Unreasonable

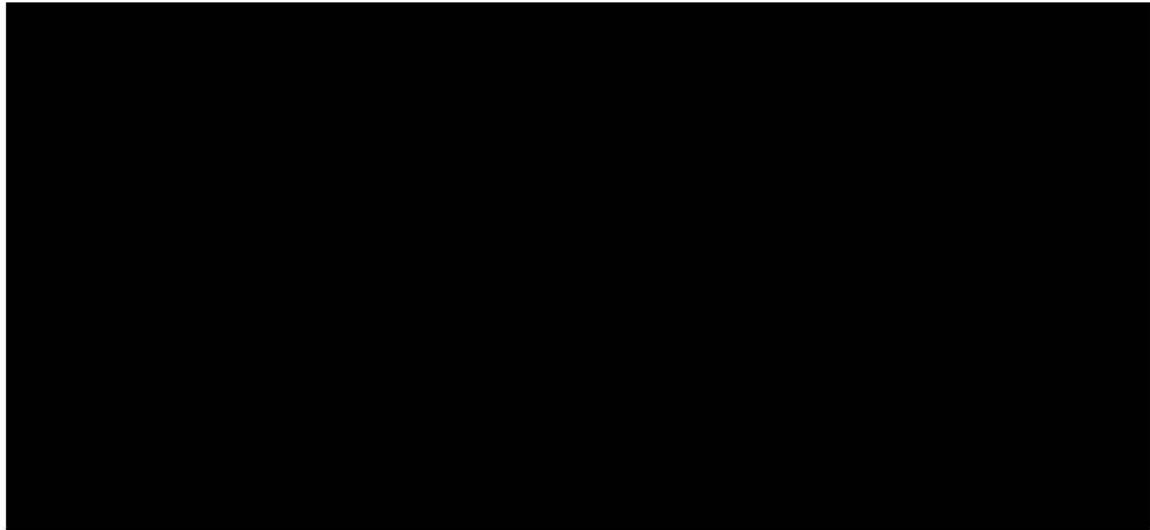
Natera contends that “[b]ecause Defendants cannot show any delay by Natera in prosecuting the cfDNA Patents, let alone any delay that was unreasonable and inexcusable under the totality of circumstances, their prosecution laches defense fails at step one.” D.I. 432 at 7. Natera’s argument is flawed because it assumes that “delay” for prosecution laches is limited to the time taken to prosecute the challenged patents, but that is incorrect. Delay can also come from the time an applicant takes to first present claims for prosecution. Assuming Natera made its inventions in 2011, Natera waited nearly a decade until 2019 to present the challenged claims for prosecution.

Both the Supreme Court and the Federal Circuit have affirmed prosecution laches based on a delay comparable to Natera’s delay here between a challenged claim’s priority date and the date the claim was first presented to the USPTO. In *Webster Elec. Co. v. Splitdorf Elec. Co.*, for instance, the Supreme Court concluded there was unreasonable delay based on an eight year gap between the filing of an original application and the date that the challenged claims were added to a later-filed child application. 264 U.S. 463, 465-66 (1924). More recently, in *Hyatt v. Hirshfeld*, the Federal Circuit measured at least ten years of delay between the challenged claims’

priority dates and the dates that the challenged claims were first presented for prosecution. *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1368 (Fed. Cir. 2021). This alone warrants denial of Natera's motion.

Natera cites three cases for the proposition that "there is no significance to whether claims are presented 'late.'" D.I. 432 at 9. Natera's cases are inapposite. First, Natera cites *Westphal v. Fawzi*, in which an applicant argued that claims presented late in prosecution could be invalidated under 35 U.S.C. § 102(b) by intervening prior art under a so-called "late claiming" doctrine. *Westphal v. Fawzi*, 666 F.2d 575, 577-78 (C.C.P.A. 1981). The Federal Circuit rejected this, finding that so-called late claims "need only be reviewed for support in the original disclosure under § 112, first paragraph." *Id.* at 577. *Westphal* has nothing to do with prosecution laches, which was not at issue. Second, Natera cites *Corrige v. Murphy*, which just re-iterates the holding from *Westphal*. 705 F.2d 1326, 1329 n.4 (Fed. Cir. 1983). Finally, Natera quotes *Symbol Technologies, Inc. v. Lemelson Medical Education and Research Foundation* as stating that an applicant "may also refile an application . . . provided that such refiling is not unduly successive or repetitive." 422 F.3d 1378, 1385 (Fed. Cir. 2005). This quotation does not support Natera's claim, and the *Symbol* court further stated that refiling of patent applications may be "a legitimate utilization of statutory provisions *or an abuse of those provisions*." *Id.*

Defendants have adduced evidence that is supported by detailed expert testimony from Nathan Kelly that Natera's delay was unreasonable. D.I. 433-3, Ex. 24 ¶¶ 89-125. Natera was monitoring ArcherDX's anchored multiplex PCR ("AMP") technology—which all of the accused products are based on—for potential infringement as early as [REDACTED]:

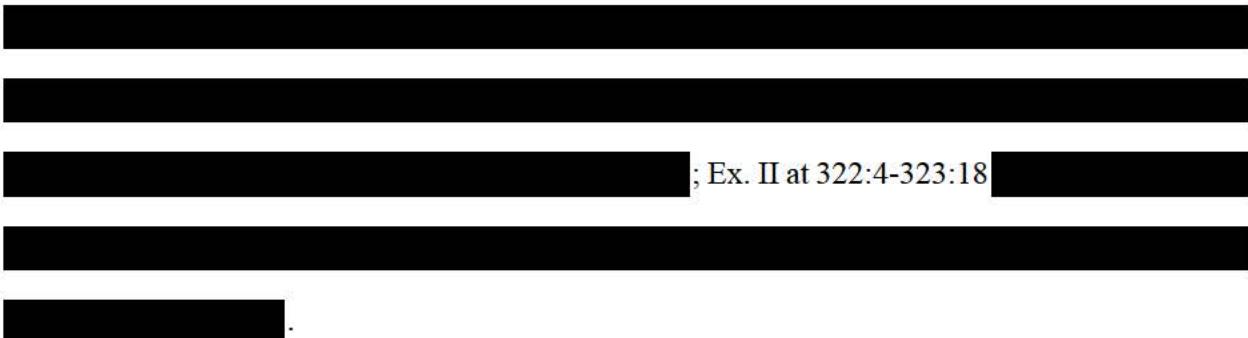


Ex. MM. Natera considered ArcherDX a competitor as early as [REDACTED].



Ex. NN.

Natera, however, did not file its patents until its market position was threatened in mid-2019. *See, e.g.*, Ex. B at 201:5-24 [REDACTED]



As Natera's founder, former CEO, and current Executive Chairman confirmed, [REDACTED]



[REDACTED]

Id. at 330:3-332:14. These are not the circumstances of diligent prosecution to protect bona fide inventions, but rather untimely and delayed prosecution.

Natera cites two cases in which courts allegedly “granted summary judgment of prosecution laches in similar situations.” D.I. 432 at 9. Natera’s cases are not similar. In *Cordance Corp. v. Amazon.com*, the court granted summary judgment where the patent owner provided a reasonable explanation for its delay. 631 F. Supp. 2d 484, 491-92 (D. Del. 2009). The court credited statements that patent owner was a “small technology compan[y],” was “struggle[ing] financially,” and was busy with other patent applications. *Id.* In contrast, Natera has not alleged that it was small, struggling financially, or too busy prosecuting other applications. Rather, a Natera 30(b)(6) witness testified that Natera decided to prosecute the cfDNA Patents in response to seeing that “other people are threatening [Natera’s] position in the market.” Ex. II at 322:4-323:18. Indeed, Natera did not file the patents until it lost a series of business opportunities to ArcherDX in 2019. D.I. 433-3 ¶¶ 66-70; Ex. OO at 123:17-125:9 (noting Natera lost two “revenue-generating” deals to ArcherDX).

In *Stambler v. RSA Security, Inc.*, the court granted summary judgment barring a laches defense based on a delay of six years and four months (6.3 years). 243 F. Supp. 2d 74, 76 (D. Del. 2003). The court noted that the patent owner “acted reasonably in prosecuting the various continuation and divisional applications during this time,” having “received seven different patents in seven years.” *Id.* In contrast, Natera delayed nearly a decade, and there is evidence and expert testimony showing that Natera did not “act reasonably” in its prosecution. During the

period of delay from 2011 to 2019, Natera obtained just 3 patents in the cfDNA Patent family.⁶ D.I. 433-3, Ex. 24 ¶¶ 27-83. Natera abandoned more than half of all applications in this family filed between 2011 and 2019. *See Id.* Then, as it started losing business to ArcherDX, between February 2019 and the filing of the present suit, Natera filed at least 42 applications, obtaining 5 issued patents in less than a year. *Id.* ¶¶ 71-83. In sum, Natera’s delay was longer than was the case in *Stambler*, and there is evidence that Natera did not “act reasonably” in its prosecution during the delay period.

Natera states that it prosecuted “no less than 13 applications during the relevant time period” as evidence that it did not delay. D.I. 432 at 10. But Natera’s experience as a patentee cuts against it. In *Intuitive Surgical, Inc. v. Computer Motion, Inc.*, the court found that a delay as short as four years and four months can be unreasonable “for an experienced patentee.” No. CIV.A. 01-203-SLR, 2002 WL 31833867 at *5 (D. Del. Dec. 10, 2002).

2. Intervening Rights Exist

Natera contends that Defendants have failed to adduce evidence of prejudice. D.I. 432 at 10. Not so. “To establish prejudice...an accused infringer must show evidence of intervening rights, that is, that the accused infringer or others ‘invested in, worked on, or used the claimed technology during the period of delay.’” *Hyatt*, 998 F.3d at 1362.

ArcherDX has put forward expert testimony from Nathan Kelly supported by documentary evidence regarding the prejudice due to Natera’s prosecution delay. *See, e.g.*, D.I. 433-3, Ex. 24 ¶¶ 17-21, 33-35, 38-39, 126-127. As Mr. Kelly explains, Natera delayed presenting the cfDNA Patent claims for prosecution from 2011 to 2019. Natera was aware of ArcherDX’s AMP technology at least as early as 2014 and was monitoring it. *See* Ex. MM; Ex. PP (first knowledge

⁶ This family is referred to in Mr. Kelley’s report as the “508 Provisional Family.”

of the accused products). There were thus at least five years of delay in which ArcherDX was investing in the purportedly claimed technology, which evidences intervening rights and prejudice.

Natera’s arguments to the contrary are purely speculative. Natera claims that ArcherDX would not “have changed anything” if it knew that Natera would be asserting its patents. D.I. 432 at 10-11. Natera’s only evidence is the speculation of Joshua Stahl. D.I. 433-3, Ex. 16 at 287:23-288:10 (“Yeah. So, again, *this is completely speculative because I didn’t know that....*”). Lay witness speculation is inadmissible under FRE 701.

Natera claims that ArcherDX “was on notice of Natera’s inventions” at least as of 2012, when a priority application (the ’235 Application) to the cfDNA Patents published and was thus “in the public domain.” D.I. 432 at 11. But the mere fact that an application was “in the public domain” does not prove that ArcherDX knew about it or had reason to know about it. Moreover, the ’235 Application could not have given notice “of Natera’s inventions” in any case because it did not claim the inventions of the cfDNA Patents. Natera’s patent expert conceded that prosecution laches can apply even where a patent application is published. Ex. KK at 73:3-11. Notably, Natera has not asserted willful infringement of the cfDNA Patents despite ArcherDX allegedly being “on notice” of these inventions since 2012.

Natera claims that ArcherDX was “aware of Natera’s patenting activity in this general area” based on the identification of one of Natera’s patent applications (the ’043 application) in one of ArcherDX’s patents. D.I. 432 at 11. The ’043 application could not have given ArcherDX notice of Natera’s inventions because it did not claim the inventions of the cfDNA Patents. Natera’s technical expert, Dr. Spellman, testified that the ’043 application “only uses conventional multiplex PCR” and that its claims “are very different than the claims of the other

patents.” Ex. BB at 112:5-112:17; 117:2-4; 119:24-120:12.⁷ Dr. Spellman further conceded that the patent office allowed one of ArcherDX’s patents claiming AMP technology over the ’043 application’s disclosure, thus further confirming its lack of relevance to the Accused Products. *Id.* at 118:23-119:22.

Natera claims that there is “‘nothing improper’ about filing claims intending to cover a competitor’s existing product.” D.I. 432 at 12 at 12. Defendants do not contend otherwise. It was not improper to file claims covering a competitor’s product; it was improper for Natera to sit idly by for years while ArcherDX invested in and developed the allegedly patented technology. Natera knew about ArcherDX’s AMP technology since 2014 but did not file the cfDNA Patents until 2019 when ArcherDX was “threatening [Natera’s] position in the market.” Ex. II at 322:4-323:18. Preventing parties from such delay while competitors develop and invest in their products is the *raison d’être* of prosecution laches. *See, e.g., Woodbridge v. United States*, 263 U.S. 50, 57 (1923) (An inventor “may forfeit his rights as an inventor by a willful or negligent postponement of his claims, or by an attempt to withhold the benefit of his improvement from the public until a similar or the same improvement should have been made and introduced by others.”) (internal quotation marks omitted); *Personalized Media Commc’ns, LLC v. Apple, Inc.*, No. 2:15-CV-01366-JRG, 2021 WL 3471180, at *21 (E.D. Tex. Aug. 5, 2021) (finding prosecution laches where evidence showed patentee planned “to prosecute its patents serially over time and keep them hidden until infringement was engrained and widespread”).

In sum, a genuine dispute of material fact remains regarding whether Natera’s delay was unreasonable, and there can be no dispute that intervening rights are present. Accordingly,

⁷ The cited transcript discusses the ’043 application’s publication, referred to as the “Ryan publication.”

Natera's motion for summary judgment against ArcherDX's prosecution laches defense should be denied.

F. Natera Is Not Entitled To Summary Judgment Of No Unclean Hands

As explained above, Natera delayed for nearly a decade in presenting its claims for prosecution. Natera monitored ArcherDX's products as early as 2014, considered ArcherDX a competitor as early as 2016, yet waited to file its patents until it started to lose business to ArcherDX in 2019. This type of business misconduct is more than sufficient to bar Natera from the relief it seeks and deny summary judgment. *Lucent Techs., Inc. v. Microsoft Corp.*, 544 F. Supp. 2d 1080, 1101 (S.D. Cal. 2008) (denying summary judgment of no unclean hands where the patentee delayed in seeking a certificate of correction for 10 years).

Further, a Natera employee, Ms. Debra Giorda, left Natera for employment at ArcherDX. After being given access to confidential information relating to Archer's products in development, Ms. Giorda went back to Natera after only *one* week. Ex. RR at 17:18-18:8. Natera filed the applications leading to the Asserted Patents shortly after Ms. Debra Giorda returned. Given the timing of the circumstances, it is more than reasonable to infer that Natera gained access to the information at this time. Natera argues that Defendants' corporate witness, Joshua Stahl, admitted that Defendants do not know what information exactly was shared by Ms. Giorda. From a practical standpoint, this is of course true. As Mr. Stahl explained, the only people that would have knowledge of conversations between Ms. Giorda and Natera executives would be the individuals involved. The Defendants have no way of knowing exactly what information was shared. Nevertheless, given the suspect events that transpired and the timing of Natera's patent applications, it is reasonable to assume that some information was transferred. For this reason as well, Natera's motion for summary judgment should be denied. *See Gilead Scis., Inc. v. Merck*

& Co., 888 F.3d 1231, 1240 (Fed. Cir. 2018) (upholding a district court’s finding of unclean hands where an employee of the patent applicant obtained confidential information of a competitor).

III. RESPONSE TO NATERA’S ARGUMENTS TO EXCLUDE TESTIMONY

A. Dr. Cooper’s Inventorship Opinions Should Not Be Excluded

Natera makes three cursory arguments in support of its request to exclude Dr. Cooper’s testimony, all of which lack merit.

Natera first contends that Dr. Cooper’s analysis was not done on a “claim by claim basis,” although Natera’s complaints to this effect are not stated with any particularity. D.I. 432 at 40. Dr. Cooper’s opinions are not deficient in this regard. Dr. Cooper pointed out what Natera itself has characterized as the alleged invention covered by its claims: a technique for avoiding unwanted side products in multiplex PCR. D.I. 419-10 ¶¶ 937-39. During expert discovery, Natera’s own experts have characterized the Natera claimed inventions the same way. D.I. 353, Ex. 14 ¶¶ 49-58; D.I. 434, Ex. L at 150:4-13, 150:25-151:5; Ex. A ¶¶ 201, 206-07. Dr. Cooper likewise explained how this issue was connected to claim 1 of each of the asserted patents. D.I. 433-3 ¶ 202. He also identified other specific features in the claims, in particular the requirement for “nested PCR.” *Id.* ¶ 203. Dr. Cooper then considered what technical work the inventors were engaged in and whether, based on this work, they could have made a contribution consistent with being named as an inventor. *See* D.I. 419-10 ¶¶ 940-77. This was not, as Natera asserts, an inappropriate inventorship analysis.

Next, Natera contends that Dr. Cooper’s opinions should be excluded because he “cherry-picked”⁸ inventor testimony and “failed to identify any corroborating evidence.” D.I. 432 at 41.

⁸ Natera criticizes Dr. Cooper for “cherry-picking” testimony twice in its brief. D.I. 432 at 41-41. Natera’s expert also criticizes Dr. Cooper for “cherry picking.” Ex. A ¶ 339. But neither Natera nor its expert ever identifies any evidence or testimony to substantiate such allegations, a

Natera, however, cites no law standing for the proposition that expert testimony on inventorship must be excluded unless it is based on the full gamut of available evidence. Although Dr. Cooper relied primarily on inventor testimony, and assumed that the inventors were truthful in their testimony about what they worked on, Natera cites no law standing for the proposition that such inventor testimony is inadmissible. In fact, inventor testimony on inventorship is admissible. As documented above, there is substantial evidence corroborating the inventor testimony that Defendants can present through other avenues. *See supra* Part II.B.2. Just because Dr. Cooper’s contribution to Defendants’ inventorship case happens to focus on the fully admissible inventor testimony does not render his opinions inadmissible.

Finally, Natera asserts that Dr. Cooper’s testimony is “unhelpful to the trier of fact” because it is merely his interpretation of “cherry-picked testimonies of Natera’s scientists.” D.I. 432 at 42. According to Natera, a “trier of fact is equally capable of reviewing and understanding a scientist’s testimony.” *Id.* Yet, “the purpose of expert testimony is to assist the trier of facts to understand, evaluate, and decide complex evidential material.” *United States v. Perez*, 280 F.3d 318, 341 (3d Cir. 2002). Here, as Natera acknowledges, we are dealing with complex technical testimony of scientists. This is precisely the type of subject matter that an expert can, and should, help the trier of fact interpret. Natera’s assertion that this is in contravention of Rule 702 is meritless.

B. Dr. Kelly’s Prosecution Laches Opinions Should Not Be Excluded

This District has recognized that “patent law experts are frequently permitted to testify about matters such as general practices and procedures employed by the PTO in

point Natera’s expert admitted at deposition. *See* Ex. BB at 239:3-13. Natera’s “cherry picking” allegations are empty rhetoric.

examining...patents.” *Sonos, Inc. v. D & M Holdings, Inc.*, 297 F. Supp. 3d 501, 511 (D. Del. 2017). Mr. Kelley’s opinions, as set forth in his reports and deposition testimony (Exs. __-__), are based on his specialized knowledge as a patent law expert who worked at the USPTO for 18 years. D.I. 433-3, Ex. 24 ¶¶ 3-4. Natera’s motion to exclude Mr. Kelley’s opinions should be denied.

The majority of Mr. Kelley’s expert report is devoted to walking through the prosecution history of the cfDNA Patents and dozens of related applications. *E.g., Id.* ¶¶ 22–26 (mapping patent family tree), 27-31, 36-37, 40-42, 44-46, 62-65, 71-83, 85 (walking through prosecution history). This kind of testimony has been allowed in this District. *See Purewick Corp. v. Sage Prods., LLC*, No. 19-1508 (MN), Order (D. Del. June 24, 2021) (D.I. 178) (allowing patent expert to “walk[] through various patent applications” to “summarize a vast amount of information”). In the same timeline, Mr. Kelley identifies Natera emails and documents referencing ArcherDX and its products. D.I. 433-3, Ex. 24 ¶¶ 32-35, 38-39, 43, 47-61, 66-70, 84. Mr. Kelley’s opinions would be helpful to a fact finder in understanding the complex timeline of Natera’s patent prosecution.

Mr. Kelley also opines on aspects of the prosecution history that are unusual based on his experience at the USPTO, such as the length of Natera’s applications (*id.* ¶ 101), the size and complexity of Natera’s priority claims (*id.* ¶¶ 98-100), and Natera’s practice of filing multiple applications with identical claims (*id.* ¶¶ 102-109). Mr. Kelley supports his numerical opinions with statistics on US patents. *See, e.g.*, Ex. SS ¶¶ 34, 39-40. These opinions are based on Mr. Kelley’s specialized knowledge of USPTO practice and procedure.

Mr. Kelley also opines on the “unexplained delay” prong of prosecution laches. *Id.* ¶¶ 111-27. Mr. Kelley applies his expertise in explaining what would or would not be a legitimate

cause for delay from a prosecution perspective. *See* Ex. QQ at 45:13-46:23 (discussing “reasonable prosecution event[s]” that can cause delay). Patent experts have previously been permitted to opine on both the “unreasonable” and “unexplained” prongs of prosecution laches. *See Hyatt*, 998 F.3d at 1357 (“According to Mr. Kunin, unreasonable **and unexplainable** delay also resulted from Hyatt’s pattern of conduct during prosecution....”).

Natera claims that Mr. Kelley is “not opining on matters of PTO practice and procedure” because he does not discuss the MPEP. D.I. 432 at 38. As explained by Mr. Kelley, however, the MPEP is not a binding source of law to patent examiners or to the public. Ex. SS ¶ 6. In any case, it is not an expert’s role to opine on what the law is; an expert’s role is to provide specialized knowledge that will help the trier of fact to understand the evidence. *See* FED. R. EVID. 702. Mr. Kelley provides specialized knowledge of PTO practice and procedure in his analysis of the prosecution history of Natera’s applications, as discussed above.

Natera accuses Mr. Kelley of offering “legal conclusions untethered to his specialized knowledge” and of “doing nothing more than what a trier of fact does” (D.I. 432 at 38), but Natera does not offer a single example of where this occurs. Mr. Kelley expressly states that he does not expect to “testify on the ultimate issue of prosecution laches.” D.I. 433-3, Ex. 24 ¶ 88.

Natera claims Mr. Kelley is “speculat[ing] on why Natera presented the asserted claims in 2019 rather than 2011,” citing portions of his opening report. D.I. 432 at 39. Mr. Kelley considered potential explanations for Natera’s delay in his opening report based on Natera’s employee testimony. This was necessary at the time because Natera had refused to provide a 30(b)(6) witness on the topic of its decision to prosecute the cfDNA Patents. D.I. 433-3, Ex. 24 ¶¶ 111-12. But Mr. Kelley made clear that “[t]he fact of the matter is that Natera’s delay is unexplained because Natera has declined to offer an explanation.” Reply ¶ 56. Natera later

provided a 30(b)(6) witness on this topic, which was addressed in Mr. Kelley's supplemental report. *See generally* Ex. TT

Finally, Natera claims that Mr. Kelley is speculating about "Natera's motives" by suggesting that "purchase of kits for *RNA* samples somehow implicated a deliberate delay by Natera in presenting *cfDNA* claims for prosecution." D.I. 432 at 39 (emphasis in original). But the portions of Mr. Kelley's report cited by Natera make no such claim, and Mr. Kelley expressly states that his opinions "do not assume or rely on a finding of bad faith." Ex. SS at p. 20.

For the foregoing reasons, Natera's motion to exclude Mr. Kelley's testimony in its entirety should be denied.

IV. CONCLUSION

For the foregoing reasons, Natera's motions should be denied.

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Respectfully submitted,

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